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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,820	04/09/2004	Kazunari Taira	04853.0059-01000	9492

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EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,820	TAIRA ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-9, 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 12/20/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 09/21/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 12/20/2005, claims 8, 9, and 12-18 are pending in the application.

Claims 16-18 are withdrawn from consideration as being directed to a non-elected invention because, as stated in the previous Office action filed 09/21/2005, applicant has received an action on the merits for the originally presented invention, claims 8, 9 and 12-15, and therefore this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant traverses the restriction requirement and argues that because the subject matter of claims 8, 9 and 12-15 are drawn to the same genus as that recited in claims 16-18, there is no undue burden for the Office to search all of the pending claims in a single examination. Applicant further argues that the secondary structure of SEQ Id NO. 4 is the same as the secondary structure of tRNA as recited in claim 16 and therefore the tRNA are not different and distinct structures.

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These arguments are not found persuasive for the following reasons: the inventions of group I and group II are unrelated because the newly submitted claims 16-18 are drawn to an RNA variant comprising specifically from 5' to 3' a tRNA sequence in which the last seven bases of the mature tRNA sequence are removed wherein the RNA variant further comprises a ribozyme or an antisense RNA attached to the 3' end of the linker sequence and the secondary structure of SEQ ID NO: 4 is not a limitation of the newly added claims.

The requirement is still deemed proper and is therefore made **FINAL**.

Response to Applicant's Arguments

Claim Rejections - 35 USC § 112

The rejection of record of claims 8, 9, and 12-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicant's arguments filed 06/27/2005 have been fully considered but are not persuasive. Applicant argues claim 8 makes clear that the bulge structure is introduced in the region in which hydrogen bonds form between nucleotides 8 to 14 and nucleotides 73 to 79 and further Applicant argues it is clear that the secondary structure (I) is a reference structure which is then modified as indicated.

On the contrary, it is not clear from claim 8, as recited, that the bulge structure is "introduced" into the "reference structure" shown in claim 8 because claim 8 is drawn to an RNA variant adopting the following secondary structure (I) wherein said RNA variant *comprises a bulge structure*. The claim language as recited does not refer to the structure depicted in claim

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8 as a reference structure and further it is unclear what structure the instant claims are drawn to because the secondary structure (I) does not have a bulge structure introduced in the region in which hydrogen bonds form between nucleotides 8 to 14 and nucleotides 73 to 79.

Moreover, as stated in the previous Office action, the structure (I) is depicted in instant claim 8, although the claim is drawn to a variant adopting such secondary structure. It is unclear whether the bulge is introduced into the secondary structure or into the variant adopting the secondary structure. It appears that applicant refers to both the structure depicted as (I) and a RNA variant that adopts such secondary structure as the RNA variant. Although applicant appears to be referring to the counting of nucleotides and introduction of a bulge into the secondary structure (I), the instant claim is drawn to such nucleotides and insertion of a bulge into an RNA variant that adopts the secondary structure (I) rather than into the secondary structure itself.

Therefore, the rejection of record of claims 8, 9, and 12-15 under 35 U.S.C. 112, second paragraph, is maintained.

The rejection of record of claims 8, 9, and 12-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed 06/27/2005 have been fully considered but are not persuasive. Applicant argues they have provided a core structure of tRNA having a secondary structure as depicted in claim 8 and further Applicants submit they have described a representative number of species that all share the secondary structure and therefore Applicants were in possession of the claimed invention.

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As stated in the previous Office action, Applicant is claiming a genus of RNA variants wherein it is impossible to determine the secondary or tertiary structure from an undisclosed primary structure. The instant claims encompass any RNA variant that adopts the secondary structure (I), as recited in claim 8, wherein the RNA variant comprises a bulge structure introduced in any region because it is unclear where nucleotides 8 to 14 or 73 to 79 would be located since such a molecule is neither described or disclosed.

Applicant argues a core sequence is not required because a written description requirement can be satisfied by the recitation of a structure. Applicant further points to a representative number of species of RNA variants that retain “an overall secondary structure (I)” and function to transport an RNA sequence to the cytoplasm, as recited in Figure 1A-C. Applicant further points to Rz4 in Figure 1D, as not adopting the instantly claimed secondary structure (I) and therefore does not function to transport the attached ribozyme into the cytoplasm.

Applicant has not described what sequence would therefore adopt the secondary structure that would retain the function to transport RNA into the cytoplasm. Figure 1 discloses three out of four RNA variants that retain the desired function but it is not clear from the disclosure what core sequence of RNA variants would adopt the secondary structure as claimed and retain the claimed function and one of skill in the art would not recognize which sequence of nucleotides would form the instantly claimed secondary structure. Further Applicant has not adequately described what types of bulge structures, that when introduced into the RNA variant, would retain the instantly disclosed function of transporting RNA into the cytoplasm. As stated in the previous Office action, the bulge structure as instantly claimed encompasses anything from a

single mismatch to introduction of a large loop structure and one of ordinary skill in the art would not recognize what types of structures could be introduced into the regions as recited.

Therefore, one of ordinary skill in the art would not be able to envision the genus of molecules instantly claimed and one would not recognize that Applicant was in possession of the claimed genus at the time the invention was made.

Therefore, the rejection of record of claims 8, 9, and 12-15 under 35 U.S.C. 112, first paragraph, is maintained.

Claim Rejections - 35 USC § 102

The rejection of record of claim 8 under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (US 5,607,842) is maintained.

Applicant's arguments filed 06/27/2005 have been fully considered but are not persuasive. Applicant argues that because the RNA shown in Figure 4 of Cohen et al. does not include an introduced bulge, it does not disclose every element recited in claim 8 and therefore does not anticipate claim 8.

As stated in the 35 U.S.C. 112, second paragraph above and in the previous Office action, it is unclear what is meant by a bulge structure because claim 8 recites a RNA variant adopting the following secondary structure (I) wherein said RNA variant *comprises a bulge structure*.

Therefore, for purposes of search and examination, the claim is being interpreted as being drawn to an RNA variant adopting the secondary structure (I) and the rejection of record of claim 8 under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (US 5,607,842) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

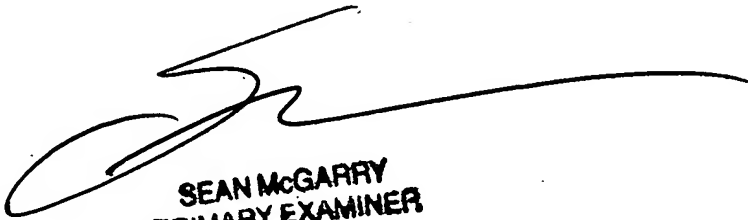
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635



**SEAN MCGARRY
PRIMARY EXAMINER**